REMARKS

Claims 1-30 are pending in the present application. Claims 1-30 are rejected under 35 U.S.C. §101 as claim claiming the same invention as that of copending applications. Claims 1-30 are also rejected under the judicially created doctrine of obviousness-type double patenting. Applicants respectfully request reconsideration of the application, withdrawal of all rejections, and allowance of the application in view of the amendments and remarks below.

The Invention

The present invention provides novel condensation drug aerosols and methods for producing such aerosols. These condensations aerosols have little or no pyrolysis degradation products. The unique method for generating or producing such aerosols employs rapid vaporization of the drug to minimize drug degradation during the process. These vaporized drugs are subsequently condensed to form particles of a desirable particle size for inhalation. These aerosols are especially useful in the treatment of acute or chronic conditions wherein rapid onset of treatment is desirable.

The Amendments to the Specification

The specification has been amended, at paragraph **[0084]**, to note a calculated thickness of a lidocaine thin layer, on a 24.5 cm^2 aluminum-foil solid support, of about 5.0 microns, based on an assumed drug density of 1g/cc.

The specification has been amended, at paragraph **[0085]**, to note a calculated thickness of a lidocaine thin layer, on a 24.5 cm^2 aluminum-foil solid support, of about 4.2 microns, based on an assumed drug density of 1g/cc.

The specification has been amended, at paragraph **[0086]**, to note a calculated thickness of a rizatriptan thin layer, on a 150 cm^2 aluminum-foil solid support, of about 0.7 microns, based on an assumed drug density of 1g/cc.

The specification has been amended, at paragraph **[0087]**, to note a calculated thickness of a rizatriptan thin layer, on a 36 cm^2 aluminum-foil solid support, of about 3.1 microns, based on an assumed drug density of 1g/cc.

The specification has been amended, at paragraph **[0088]**, to note a calculated thickness of a rhizatriptan thin layer, on a 36 cm^2 aluminum-foil solid support, of about 3.2 microns, based on an assumed drug density of 1g/cc.

The specification has been amended, at paragraph **[0090]**, to note a calculated thickness of a zolmitriptan thin layer, on a 36 cm^2 aluminum-foil solid support, of about 2.7 microns, based on an

assumed drug density of 1g/cc.

The specification has been amended, at paragraph **[0091]**, to note a calculated thickness of a zolmitriptan thin layer, on a 24.5 cm^2 aluminum-foil solid support, of about 1.3 microns, based on an assumed drug density of 1g/cc.

The specification has been amended, at paragraph **[0092]**, to note a calculated thickness of a zolmitriptan thin layer, on a 24.5 cm^2 aluminum-foil solid support, of about 1.1 microns, based on an assumed drug density of 1g/cc.

The specification has been amended, at paragraph **[0099]**, to note a calculated thickness of a frovatriptan thin layer, on a 24.5 cm^2 aluminum-foil solid support, of about 2.0 microns, based on an assumed drug density of 1g/cc.

The specification has been amended, at paragraph **[0100]**, to note a calculated thickness of a frovatriptan thin layer, on a 24.5 cm^2 aluminum-foil solid support, of about 2.0 microns, based on an assumed drug density of 1g/cc.

The amendments to the specification at paragraphs **[0084]-[0088]**, **[0090]-[0092]**, **[0099]** and **[0100]** parallel the amendments that were made with respect to the parent U.S. patent application Serial No. 10/154,594, now U.S. Patent No. 6,740,309.

It is well-established in the case law that amendatory material is not new matter where it is concerned with an inherent characteristic of an illustrative product of an invention already sufficiently identified in the original patent disclosure. (*In re Nathan, Hogg, and Schneider*, 140 USPQ 601 (CCPA, 1964); In *In re Reynolds*, 170 USPQ 94 (CCPA 1971) the CCPA cited with approval the following holding from *Technicon Instruments Corp. v. Coleman Instruments, Inc.*, 255 F. Supp. 630, 150 USPQ 227 (N.D. Ill. 1966):

> By disclosing in a patent application a device that inherently performs a function, operates according to a theory, or has an advantage, a patent applicant necessarily discloses that function, theory, or advantage even though he says nothing concerning it. The application may be amended to recite the function, theory, or advantage without introducing prohibited new matter.

This principle has been endorsed by the CAFC, e.g., in *Kennecott Corp., v. Kyocera Int'l l Inc.*, 835 F. 2d. 1419, 5 USPQ2d 1194 (Fed. Cir. 1987).

The amendatory material regarding the assumed density of the drugs is already stated in the specification, e.g., see paragraph **[0084]** which states " . . . multiplied by the density of the drug (taken to be 1 g/cm^3)." Additionally, the thickness of the coating would be readily derivable by a person skilled in the art of the claimed invention by multiplying the mass of the material by its density and then dividing this by the surface area over which it is coated. As stated above information regarding the density is readily available

from the specification and other recognized sources (e.g., the CRC Handbook of Chemistry and Physics, the Aldrich Chemical Catalog, etc.) and can be assumed to about 1g/cc. The drug masses and substrate areas are also disclosed in the specification. This information is all that is needed for one to calculate the thickness.

Thus, no new matter is introduced by these amendments to the specification. The Examiner is respectfully requested to enter the amendments to the specification.

The Amendments to the Claims

Without prejudice to the Applicants' rights to present claims of equal scope in a timely filed continuing application, to expedite prosecution and issuance of the application, the Applicants have amended Claims 1-3, 5 and 16-18 and cancelled Claims 4, 6-15 and 19-30. The Applicants also have presented new Claims 31-53. The amended claims and the new claims are supported by the specification (see below for examples of such support).

Claim	Examples of Support in the Specification
Claim 1	Paragraphs 0005, 0009, 0013, 0015; Examples 2-7, 9-13 and 15-18
Claim 2	Paragraph 0028
Claim 3	Paragraph 0028
Claim 5	Paragraph 0009
Claim 16	Paragraphs 0005, 0009, 0013, 0015; Examples 2-7, 9-13 and 15-18
Claim 17	Paragraph 0028
Claim 18	Paragraph 0028
Claim 31	Paragraphs 0001 [incorporates by reference U.S. provisional application Ser. No. 60/317,479 (see, e.g., page 30, lines 25-27)], 0013
Claim 32	Paragraph 0013
Claim 33	Paragraphs 0001 [incorporates by reference U.S. provisional application Ser. No. 60/317,479 (see, e.g., page 30, lines 25-27)], 0013
Claim 34	Paragraph 0009
Claim 35	Examples 3-7, 9-11, 16 and 17
Claim 36	Paragraph 0061
Claim 37	Paragraphs 0001 [incorporates by reference U.S. provisional application Ser. No. 60/317,479 (see, e.g., page 30, lines 25-27)], 0013
Claim 38	Paragraph 0013
Claim 39	Paragraphs 0001 [incorporates by reference U.S. provisional application Ser. No. 60/317,479 (see, e.g., page 30, lines 25-27)], 0013
Claim 40	Paragraph 0009
Claim 41	Paragraph 0009
Claim 42	Examples 3-7, 9-11, 16 and 17
Claim 43	Paragraph 0061
Claim 44	Paragraphs 0001 [incorporates by reference U.S. provisional application Ser. No. 60/317,479 (see, e.g., page 30, lines 25-27)], 0005, 0009, 0013, 0015, 0086
Claim 45	Paragraphs 0001 [incorporates by reference U.S. provisional application Ser. No. 60/317,479 (see, e.g., page 30, lines 25-27)], 0005, 0009, 0013,

	0015, 0090
Claim 46	Paragraphs 0001 [incorporates by reference U.S. provisional application Ser. No. 60/317,479 (see, e.g., page 30, lines 25-27)], 0005, 0009, 0013, 0015, 0097
Claim 47	Paragraphs 0001 [incorporates by reference U.S. provisional application Ser. No. 60/317,479 (see, e.g., page 30, lines 25-27)], 0005, 0009, 0013, 0015, 0097
Claim 48	Paragraphs 0001 [incorporates by reference U.S. provisional application Ser. No. 60/317,479 (see, e.g., page 30, lines 25-27)], 0005, 0009, 0013, 0015, 0097
Claim 49	Paragraphs 0001 [incorporates by reference U.S. provisional application Ser. No. 60/317,479 (see, e.g., page 30, lines 25-27)], 0005, 0009, 0013, 0015, 0086
Claim 50	Paragraphs 0001 [incorporates by reference U.S. provisional application Ser. No. 60/317,479 (see, e.g., page 30, lines 25-27)], 0005, 0009, 0013, 0015, 0090
Claim 51	Paragraphs 0001 [incorporates by reference U.S. provisional application Ser. No. 60/317,479 (see, e.g., page 30, lines 25-27)], 0005, 0009, 0013, 0015, 0097
Claim 52	Paragraphs 0001 [incorporates by reference U.S. provisional application Ser. No. 60/317,479 (see, e.g., page 30, lines 25-27)], 0005, 0009, 0013, 0015, 0097
Claim 53	Paragraphs 0001 [incorporates by reference U.S. provisional application Ser. No. 60/317,479 (see, e.g., page 30, lines 25-27)], 0005, 0009, 0013, 0015, 0097

The amendments to the claims do not introduce new matter. Applicants respectfully submit that the amendments to the claims put the case in condition for allowance. The Examiner is respectfully requested to enter the amendments to the claims and allow all amended claims.

Double Patenting

Claims 1-6 and 16-21 were provisionally rejected under 35 U.S.C. §101 as claiming the same invention as that of claims 1-3, 5-7 and 9-14 of copending Application No. 10/792,012. Office Action at 2. As amended, Applicants submit that the claims of the present application and the claims of copending Application No. 10/792,012 are not coextensive in scope.

Claims 7-15 and 22-30 were provisionally rejected under 35 U.S.C. §101 as claiming the same invention as that of claims 1-18 of copending Application No. 10/791,915. *Id.* at 2. As amended, Applicants submit that the claims of the present application and the claims of copending Application No. 10/791,915 are not coextensive in scope.

Claims 1-30 were rejected under the judicially created doctrine of obviousness-type double patent as being unpatentable over claims of U.S. Patent Nos. 6,740,309 B2, 6,759,029 B2, 6,743,415 B2 and 6,805,854 B2, as these claims are "either anticipated by, or would have been obvious over, the reference

claims." *Id.* at 3. Also, Claims 1-30 were provisionally rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application Nos. 10/768,220, 10/735,198, 10/735,496, 10/792,239 and 10/792,096. *Id.* at 4.

Applicants have filed with this response Terminal Disclaimers with regard to U.S. Patent Nos. 6,740,309 B2, 6,759,029 B2, 6,743,415 B2 and 6,805,854 B2 and copending Application Nos. 10/768,220, 10/735,198, 10/735,496, 10/792,239 and 10/792,096. Applicants believe that this addresses the Examiner's concerns and respectfully request reconsideration of the application, withdrawal of all rejections, and allowance of the application in view of these actions and remarks.

Conclusion

The Applicants appreciate the Examiner's careful and thorough review of the application and submit that the Examiner's concerns have been addressed by the amendments and remarks above. The Applicants accordingly request the Examiner to withdraw all rejections and allow the application. In the event the Examiner believes a telephonic discussion would expedite allowance or help to resolve outstanding issues, prosecution of the application, then the Examiner is invited to call the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-5117, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-5117.

Respectfully submitted,

Date: August 23, 2005

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